Use of **ECHELON FLEX™ Powered Staplers** has been associated with improved clinical and economic outcomes in thoracic surgery.\(^4,5\)

### Clinical and financial burden

#### Bleeding-related complications

- Between 2-10% of lobectomies\(^1,2\)
- **2.7x higher** risk of in-hospital mortality\(^2\)
- **$16K** incremental hospital costs\(^2\)

#### Post-operative air leaks

- 24% of lobectomies\(^3\)
- **1.9x higher** risk of in-hospital mortality\(^3\)
- **$6.5K** incremental hospital costs\(^3\)

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4. Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 3,006 cases between 2012 and 2015 from the Premier Perspective® Hospital Database.  
5. Staple line air leaks in porcine lungs using a physiologically-based ex-vivo lung chamber model. **ECHELON FLEX™ GST System** vs Endo GIA® with Tri-Staple™ Technology 20% vs 44%. GST 45 Blue & Green reloads vs Tri-Staple™ 45 Purple & Black. (n=10) Based on similar design features between ECHELON GST45 & GST60, no significant difference in performance is expected.
Fewer hemostasis-related complications in VATS lobectomy

**PEER-REVIEWED PUBLICATION REPORTS**

Use of **ECHOLON FLEX™ PVS** has been associated with a reduction in hemostasis-related complications

**Why ECHOLON FLEX™ PVS?**

**Designed for thoracic surgery**

- Enables improved access and more precise placement on fragile vessels†
  - Narrower anvil
  - Increased articulation
  - Smaller shaft diameter

- Reduced tension on vessels by 60%†

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1. Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database (4.8% vs 14.2%; p=0.0098).
2. Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database (3.0% vs 9.4%; p=0.023).
3. Compared to the Endo GIA™ Curved Tip Reload with Tri-Staple™ technology. PVE35A, EGIA30CTAVM, and PSE45A articulation data from IFUs of each device.
5. Based on articulation data from IFUs of each device.
6. Approach angles assessed in a virtual CAD environment in the 5th intercostal space.
7. Net tension applied to pulmonary vessel during stapler placement, clamp, fire, and release in ex vivo porcine model. ECHOLON FLEX™ Powered Vascular Stapler (5.55 kPa·s, n=18) vs Endo GIA™ with Tri Staple™ Technology (14.01 kPa·s, n=17) (p=0.008).

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*In cases with ECHOLON FLEX™ PVS used in combination with another ECHOLON FLEX™ Powered Stapler*
**Evidence through innovation**

**Physiologic Lung Model** reveals fewer air leaks.

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**IN THE ONLY VENTILATION MODEL SIMULATING PHYSIOLOGIC BREATHING**

2x fewer staple-line air leaks with ECHELON FLEX™ GST System

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**Why ECHELON FLEX™ GST System?**

<table>
<thead>
<tr>
<th>Differences in design principles</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endo GIA™ with Tri-Staple™ Technology</strong></td>
<td><strong>ECHELON FLEX™ GST System</strong></td>
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<tr>
<td><strong>GRADUATED STAPLE HEIGHT</strong></td>
<td><strong>UNIFORM STAPLE HEIGHT</strong></td>
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<tr>
<td>• All leaks originated from outer row of staples</td>
<td>• Exceptional staple line integrity across the broadest range of tissue thicknesses</td>
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<tr>
<td>• Third-party study found that outer row of graduated staples may not compress lung parenchyma enough to seal correctly</td>
<td>• More reload choices to meet specific tissue needs</td>
</tr>
<tr>
<td><strong>SINGLE-STAGE COMPRESSION</strong></td>
<td><strong>MULTI-STAGE COMPRESSION</strong></td>
</tr>
<tr>
<td>• Higher force exerted on tissue during firing</td>
<td>• Designed to reduce the forces exerted on tissue during firing</td>
</tr>
</tbody>
</table>

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1. Staple line air leaks in porcine lungs using a physiologically-based ex-vivo lung chamber model. ECHELON FLEX™ GST System vs. Endo GIA™ with Tri-Staple™ Technology: 20% vs. 44%. GST 45 Blue & Green reloads vs. TriStaple™ 45 Purple & Black. (n=110). Based on similar design features between ECHELON GST45 & GST60, no significant difference in performance is expected.


3. The ECHELON FLEX™ GST System was designed and tested to meet rigorous design requirements for staple line integrity. The GST System accommodates a tissue thickness range of 1.0 mm to 4.0 mm (measured at 8g/mm², tissue comfortably compressed to closed staple height during firing per IFU) while the Medtronic TriStaple™ portfolio is intended for a tissue thickness range of 0.75 mm to 3.0 mm (per IFU and materials downloaded from Medtronic website on Nov 16, 2016).
Echelon Flex™

**Improved economic value in VATS lobectomy**

**Improved hemostasis outcomes** were associated with use of Echelon Flex™ PVS plus another Echelon Flex™ Powered Stapler—**without increasing costs**

- **Medtronic non-powered staplers**
- **Echelon Flex™ Powered Staplers**
- Statistically significant difference

*Source: Advances in Therapy*

**ECHELON FLEX™ Powered Staplers**
**Tissue-specific** devices designed to improve precision in thoracic surgery

**ECHELON FLEX™ PVS** enables more precise placement on fragile vessels

**ECHELON FLEX™ GST System** enables you to transect as you intend, even on challenging tissue

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1. Ethicon retrospective analysis of outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database. Hemostasis-related complications: 4.8% vs 14.2%; *p* = 0.010. Transfusion: 3.0% vs 9.4%; *p* = 0.023. Total hospital costs: $23,219 vs $25,207; *p* = 0.242.

2. Compared to the Endo GIA™ Curved Tip Reload with Tri-Staple™ technology. PVE35A, EGIA30CTAVM, and PSE45A articulation data from IFUs of each device.
Impact of Powered and Tissue-Specific Endoscopic Stapling Technology on Clinical and Economic Outcomes of VATS Lobectomy Procedures

Daniel Miller, MD; Sanjoy Roy; Edmund Kassis, MD; Sashi Yadalam; Sushama Ramisetti; Stephen Johnston

Methodology

Data source: Premier Healthcare Database
- Over 6 million cases annually in wide range of surgical areas
- >700 contributing hospitals
- Represents 20% of HIPAA-compliant US inpatient discharges
- Used in 375+ peer-reviewed publications

Study design established prior to data collection
- Focused on a primary research question: Does stapler choice matter in VATS lobectomy?
- Protocol-driven
- Data analyzed included hospital length of stay, operating time, hospital costs, complications, and readmissions
- Analysis included ICD-9 and ICD-10 codes related to hemorrhage, hematoma, acute post-hemorrhagic anemia, seroma, and transfusion

2-step control for confounding factors
1. Primary analysis multivariate statistical model included:
   - Surgeon and hospital types (facility size, procedure volumes, teaching/non-teaching, etc.)
   - Patient demographics (age, gender, payer type, etc.)
   - Clinical characteristics (comorbidities, concomitant resections, etc.)
2. Confirmatory analysis matched patient cohorts by propensity scores

Meets rigorous publication standards
- Followed academic research guidelines
- Adhered to a results-agnostic publication policy
- Involved external clinical expert to ensure unbiased interpretation
- Underwent peer review with clinical scientific journal
Quantification of Air Leaks in a Physiologic Lung Model: Effects of Ventilation and Stapler Design

Chad E. Eckert, PhD; Jason L. Harris, PhD; Jordon Wong, BS; Suzanne Thompson, DVM; Edmund S. Kassis, MD; Masahiro Tsuboi, MD; Seth Force, MD

Methodology

Physiologic Lung Model

- First of its kind to simulate natural breathing conditions
- Approximates clinical conditions by simulating 2 breathing modalities in ex vivo lung tissue
  - Ventilated breathing (intra-operative/positive pressure)
    - Cannulation port with mechanical compressor
  - Physiologic breathing (post-operative/negative pressure)
    - Piston simulates diaphragmatic motion
- Collects and measures air leaks by incidence and volume
- Published in IEEE Transactions on Biomedical Engineering

Testing method

ECHELON FLEX™ GST System vs Endo GIA™ with Tri-Staple™ Technology

- Wedge resection in porcine lung tissue
- Study 1: Thinner tissue (n=50); Study 2: Thicker tissue (n=60)
- Two crossing staple lines in each sample
- Clinically relevant chamber pressures (Ventilator: avg. 36 cm H₂O; Physiologic: avg. -14 cm H₂O)
- Leaks defined as bubbles originating from staple line, captured by the system

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